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MACCORD MASON PLLC
300 N. GREENE STREET, SUITE 1600
P. O. BOX 2974
GREENSBORO, NC 27402

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GAKH, YELENA G	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09737185
Filing Date: 12/14/2000
Appellant(s): Bowman, Danny; Bowman, Jason; Lewis, David; Paisley, Richard

Howard A. MacCord
For Appellant

This is in response to the appeal brief filed 04/11/2012.

EXAMINER'S ANSWER

(1) Grounds of Rejection to be Reviewed on Appeal

Every ground of rejection set forth in the Office action dated 10/11/11 from which the appeal is taken is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

The following ground(s) of rejection are applicable to the appealed claims.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner: rejection of claims 1-21, 38 and 40-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, regarding the electronic memory tag (rejection B in the Non-Final rejection from 10/11/11).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 40-42, 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels, with at least some members of the plurality located at a vessel distribution facility, a collection facility, a specimen testing laboratory facility. The recitation of the claims contradicts the disclosure as originally filed. Not only the specification does not have the term "plurality of the vessels" or any of its equivalent, but the only disclosure regarding

distributing plurality of vessels is related to Figure 4, according to which the plurality of vessels is moving *from* one facility *to* another. No distribution of the plurality of vessels among indicated facilities is disclosed in the specification. On the contrary, according to Figure 4, there are no times, when such distribution among facilities occurs.

The examiner respectfully reminds the Applicants that according to MPEP §2163:

> "**2163.02. Standard for Determining Compliance with Written Description Requirement**:
>
> The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The Applicants did not show "possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 38 and 40-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Several claims recite "[a] diagnostic specimen system comprising a plurality of biomedical specimen collection vessels, at least some members of the plurality being located at a vessel distribution facility, other members of the plurality being located at a specimen collection facility, further members of the plurality being located at a specimen testing laboratory facility, and additional members of the plurality being transported between the facilities". First, the claim language is not supported by the specification, and it is not apparent, how this system is formed. Is this a permanent system, or is this a changing system? Are these vessels constantly located at the indicated facilities? Are the vessels located at recited facilities different from each other? Moreover, since the vessels are supposed to contain samples, would it be vessels with the same partitioned sample distributed among all facilities? The language renders the claims unclear and indefinite.

Furthermore, the claims recite that each of the collection vessel includes a wireless electronic memory tag, directly attached to the vessel. It is not clear, what it means "directly attached". The electronic memory tag disclosed in the specification is described as comprising a carrier label (4) which has a front face (5) and a rear face (6) with the electronic memory device (9) attached to the rear face. Therefore, it is not apparent what specifically is "directly attached" to the vessel - the label with the electronic memory device? Furthermore, the electronic memory device (9) is described as an ultra-thin radio frequency transponder made up of an integrated circuit and an antenna. However, Uddin et al. in "UHF RFID antenna architectures and applications" demonstrates that developing antenna for the specific purpose is not a trivial task. Therefore, it is not apparent, which specific "electronic memory tag" is recited in the claims, which renders them unclear and indefinite.

The Applicants are respectfully referred to the following excerpt from MPEP:

"§2171 **Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph:**

The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 Bd. App. 1984)"

Furthermore:

"§2172 **Subject Matter Which Applicants Regard as Their Invention:**

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993)."

In the instant case "the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand

how to avoid infringement", and therefore rejection under 35 U.S.C. 112, second paragraph, is appropriate.

In claims 4 and 12 it is not clear, whether the label is the same label that includes the electronic memory device, as disclosed in the specification.

From claims 6-7 and 14-15 it is not apparent, whether the vessel contains a specimen.

From claim 38 it is not clear, where "a tamper-indicating seal" is located on the vessel. This is an essential structural relation omitted from the claim.

Claim 40 is not clear. What does it mean - "an electronic database accessible from the specimen collection facility for storing data entered at the collection facility"? It is accessible for what? The recitation of the claim is not quite clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38 and 40-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129 B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: “in one example embodiment, RFID logger 108 may prompt the collection (or

other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

Claims 1, 6-7, 9, 14-15, 19, 21 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. … It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

"A population of "biomedical specimen collection with "members" located at various locations of the specimen path is an inherent feature of the invention. As soon as the tag becomes attached to the test tube, the location where it occurs becomes "a

distribution facility". Attaching the tag with all information should occur before collection of the sample into the vessel. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The situation, when the tubes are used for collecting samples without providing any information related to the sample and "the person under concern" (col. 1, line 68) seems improbable. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously. Moving the test tubes from the collection facility (a desk where the samples are taken) to the analysis site is what Barney discloses for his population of the test specimen tubes with electronic tags.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 8, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Petrick and Barney is provided above.

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood

component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

Claims 16-17, 20 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Petric and Barney is provided above.

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates "tester's signature" in form 102, Fig. 3B. The signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

The disclosure of Barney is provided above.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

Claims 3-4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

The disclosure of Barney is provided above.

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

The disclosure of Barney is provided above.

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

Claim 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

The disclosure of Barney is provided above.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. … Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A.

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request

forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of paper by Moore (December 1999).

Stevens discloses a plurality of collection containers with a partitioned specimen label, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Stevens does not disclose electronic tag memory.

Moore in his article "Barcodes, 2D or RFID?" specifically indicates: "This is not a contest between technologies. Barcodes, two-dimensional (2D) symbols and RFID smart labels may compliment each other in everyday use. We already see examples of linear and 2D symbols being used for different purposes on the same label." "Radio frequency identification (RFID) has long been viewed as the most significant alternative to barcode technology. It has made major incursions into manufacturing and

transportation for identifying and tracking of items during harsh manufacturing processes as well as for vehicle identification of over-the-road trucks, trailers, intermodal containers and railroad rolling stock. Recent advancements in the technology, however, have reduced the size and cost of RFID tags from over $100 in many cases to about $50. The new generation of printing and reading equipment is also smaller, lighter and much more cost-effective for labels than was previously available. So-called smart labels have an inexpensive RFID chip embedded in a self-adhesive paper label (other form factors would also be possible). The label would typically have at least one barcode on it and the RFID chip would be encoded at the same time the barcode and human-readable information is printed on the label.

A lot of attention is being focused on smart labels because of their potential to carry complete electronic manifests and packing lists as well as a full range of other information, some of which can be used for tracking."

Thus, Moore specifically emphasizes benefits of using smart labels having an inexpensive RFID chip embedded in a self-adhesive paper label (other form factors would also be possible). "The label would typically have at least one barcode on it and the RFID chip would be encoded at the same time the barcode and human-readable information is printed on the label". This allows a direct modification of Stevens' two-partition barcode with attaching RFID chip to the permanent affixed portion of the label. Such modification will also be tamper-indicating.

Since the tubes with the labels will be manufactured, they will be inherently distributes between all facilities of custody chain for the biological sample collection tubes.

Claims 5, 8, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of paper by Moore, as applied to claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

The disclosure of Stevens in view of Moore is provided above.

Although Stevens in view of Moore do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information

is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for modified Stevens' test tubes, which are specifically designed for handling such information.

Claims 16-17, 20 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Moore, as applied to claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 45-49 above, and further in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

The disclosure of Stevens in view of Moore is provided above.

Stevens in view of Moore do not particularly teach encoding electronic signature in the electronic tag.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into modified Stevens' system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

(2) Response to Argument

A. The claims were not rejected as duplicates. Rather the Appellants received warning that if one set of claim is allowed, the second set of claims will be objected as the duplicate of the first set of claims. Objections and warning are not considered by the Board. The examiner only notices that the difference in level of security for structurally analogous vessels as claimed does not make them distinct.

B. Regarding rejection of the claims as adding new matter, the rejection concerns not simply the expression "plurality of vessels", as presented by the Appellants, but rather distribution of the plurality vessels among several facilities, which was totally absent from the specification as originally filed. Moreover, the claimed subject matter contradicts the original disclosure, according to which the only plurality of vessels depicted on Figure 4 is moving from facility to another one, rather than becoming distributed among all facilities. The newly introduced matter raises many issues regarding the claimed distribution, since the vessel are supposed to contain samples. Does distribution of the vessels mean that there should be vessels with the same partitioned sample simultaneously distributed among all facilities? Furthermore, Appellants argue that the absence of the word "plural" from the claims of Petrick suggests that Petrick is not doing the same method nor obvious over Petrick.

C. The arguments related to rejection of the claimed "electronic memory tag" as not supported by the disclosure are moot, since the rejection is withdrawn.

D. Regarding indefiniteness of the claims reciting distribution of the plurality of vessels among several facilities, first of all, the language of the claims is not supported by the disclosure. The specification discloses vessels moving from one facility to another along the "chain custody", while the claims recite distribution of the plurality of vessels among several facilities. This language raises many questions. For example, it would not be clear, whether the vessels should contain the same partitioned sample and be distributed among different facilities? Furthermore, distribution the vessels among different locations do not have any effect on their structure whatsoever. The vessel at location A will be exactly the same as the vessel at location B, if it is moved to this location. Therefore, distribution of similar vessels among different locations does not have any patentable weight. The examiner did not raise any questions regarding patentability of the structure of the vessel itself. As to the Appellants' examples of the location of different structural elements in the same structure, they are not relevant to the instant application.

E. Regarding antedating Patrick's reference, the examiner gave full and complete two-way analysis of Patrick's and Appellants' claims, which demonstrated that the claims were not patentably distinct in both ways, see e.g. Non-Final rejection from 03/10/10.

MPEP: 715 [R-2] Swearing Back of Reference — Affidavit or Declaration Under 37 CFR 1.131

"SITUATIONS WHERE 37 CFR 1.131 AFFIDAVITS OR DECLARATIONS ARE INAPPROPRIATE:

An affidavit or declaration under 37 CFR 1.131 is not appropriate in the following situations: (B) Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention. See MPEP § 715.05 for a discussion of "same patentable invention " and MPEP § 2306".

"715.05 [R-2] **U.S. Patent or Application Publication Claiming Same Invention**

When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date

is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, *must be by way of 37 CFR 1.608 instead of 37 CFR 1.131*. If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. *The reference can then be overcome only by way of interference*. See MPEP §§ 2306-2308".

The Appellants state that in Pertick's patent the custodian tears the RFID chip off the form to paste it to the collection container. The examiner reconsidered once more Petrick's US 6,535,129, and could not find any basis for the Appellants' conclusion. Moreover, such action would be quite illogical and unexplainable. In fact, the custodian is *placing* the RFID chip on the business form, as can be clearly seen from the drawing, with the chip remaining on the business form throughout the whole set of custody chain operations. Furthermore, in the next passage the Appellants seem to contradict themselves stating that tearing RFID from the business form in Petrick would indicate violation of the security of the protected vessel, as indicated by Petrick. As to the distribution of the vessels among all the facilities of the custody chain, Petrick recites the business form with RFID tag specifically for using it in such custody chain. If the Appellants consider this as not inherent to Petrick's claims, then they admit that they added new matter to the disclosure as originally filed, which is in a total contradiction with their arguments related to 35 U.S.C. 112, first paragraph, rejections.

Further Appellants state that "[t]he custodian tears the RFID chip off the form and uses it to seal the container holding the specimen. (See column 3, lines 38- 55) She also enters data into the business form." The examiner provides indicated lines from Petrick's reference:

> As shown in FIGS. 3A and 3B, one particularly advantageous arrangement is to embed the RFID chip 106 within the form 102 and/or within an associated adhesive label so that it is permanently associated with the form and/or label. In this particular example, to de-associate the RFID chip 106 from the associated form 102 one would need to tear (i.e., destroy) the form--which destruction will be evident immediately upon inspection of the form. Through this mechanism, it is difficult if not impossible in the preferred example embodiment to lose, de-associate or otherwise tamper with the association between RFID chips 106 and associated forms 102. Furthermore, the form or label described in the above-referenced U.S. Pat. No. 5,976,014 with RFID chip 106 affixed thereto can be

> used to positively associate form or label 102 including RFID chip 106 with a particular sample container 100 so as to establish a positive, permanent association between the RFID chip and the collected sample.
>
> (6) FIG. 2 is a flowchart of an example data collection process 200 that may be performed by RFID logger 108 shown in FIG. 1. In the FIG. 2 example, the RFID logger 108 may query the RFID chip 106 (block 202) to receive the RFID chip's identification (and other) information and/or to send information to the RFID chip. The RFID logger 108 (and/or the RFID chip 106 in some arrangements) may log this identification information along with date, time and other pertinent information (block 204).

This disclosure appears to be in a full contradiction with the Appellants conclusion regarding tearing RFID chip from the business form by **the custodian** and using it to seal the container. How can RFID chip seal the container? And where is this disclosed in the provided paragraphs form Petrick's specification?

Furthermore, in claim 7 Petrick's chip is directly associated with the container or the specimen. Thus, the Appellants' statement that "the claims of Petrick do not read on the RFID chip being associated with the container to start with. Instead, they are limited to the RFID chip being a part of the business form so that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form" is just not correct.

Moreover, the Appellants' claimed invention in light of disclosure, including Figure 1, is exactly the same as that of Petrick, especially the one recited in claim 7. Thus, the Appellants' claim is not new and non-obvious over Petrick, and Petrick's invention would not be new and non-obvious over the Appellants' claimed subject matter. Petrick's business form with an embedded RFID chip attached to the container through the whole process of transferring the container from facility to another facility is totally equivalent to the Appellants' claimed container with attached RFID chip embedded in the business form, see Figure 1.

As to the vessel distribution facility – as soon as the business form with RFID chip becomes attached to the vessel, the place where it is attached becomes vessel distribution facility. The place where it happens does not make the subject matter of the claimed invention patentably distinct from Petrick's claimed invention.

Also, while the Appellants do not mention the word "business form", they have the carrier label 4 with a text area 8 provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4, see specification, page 11, lines 3-7. How does the carrier label 4 differ from Petricks' business form? The Appellants indicate that "there is no requirement that the claim language be set forth in *haec verba* in the specification". With this in mind, it would be even more natural to expect a different synonym for defining the same element in the patent by another inventor.

The examiner wonders where Petrick requires that the business form should be destructed - and what would be the purpose of such destruction? The examiner believes that the Appellants incorrectly interpret the language of Petrick's claims, which in fact indicate that destruction of the business form in the case of de-associating RFID from the businesses form would be visible, and thus tampering would be obvious. The aim of Petrick's invention is specifically to prevent such tampering.

The Appellants further continue to state (page 36 of the Appeal) that Petrick's invention requires removing RFID from the business form and refer to col. 5, lines 19-36, which are provided here for convenience:

> The FIG. 3B form includes enough information to establish a strict chain of custody for an associated sample. For example, the form requires the donor, the collector, the temporary storage custodian and the laboratory technician to all supply and write down or print information establishing a chain of custody for the associated sample 100. In addition, the FIG. 3B form includes a separable label portion used for sealing an associated sample 100 container with the donor's initials and the date to prevent tampering. In this particular embodiment, RFID chips 106 are providing within this label for each of three sample 100 containers so as to automatically, independently and individually track the chain of custody of each sample container. Additional, RFID chips 106 may be provided in other portions of the label to, for example, provide laboratory confirmation information, courier information and the like. The FIG. 3B form is especially advantageous for use in drug testing in connection with potential employment or the like.

The examiner did not find here any indication for removing RFID from the business form.

Regarding the method claims adding electronic signature to RFID chip does not make the claimed method novel over Petrick's claims, since adding such signature for increasing security of the sample is quite obvious for a routineer in the art.

Further the Appellants state that the examiner "repeatedly wholesale imports the parties' specifications and derives implications from the specifications in making her analysis" (page 40). The examiner is not quite sure, what is meant by this, and where this "import" of the parties' specifications takes place. The examiner believes that in her analysis she used exclusively the language of the claims with necessary referral to some disclosure of the specification which is required for reading the claims in light of the specification. The examiner also notices in their analysis of both the Appellants' and Petrick's claims the Appellants constantly refer to the specification, providing the whole excerpts from the paragraphs. Furthermore, the examiner believes that their analysis is incorrect and is not supported by the language either of the Pertick's claims, or the specification.

It appears that the Appellants repeat the same arguments through most of their Appeal related to analysis of Petricks' claims versus instant application. They continue to state that the claims recite that if RFID chip will be de-associated from the business form in Petrick's invention, tampering will be obvious. So will be de-association of RFID chip from the label of the instant application. The structure of the containers in both cases is identical; they have the same aim of being secured from tampering in the same chain of custody chain with the same distribution of vessels among the same facilities.

Regarding the rejection over Berney, the Appellants argue that the time of attaching of RFID is different. The time of attaching the chip is not relevant to the structure of the container. Berney obviously is teaching transporting the vessels from facility to facility, which inherently makes them distributed over facilities. Moreover, the claims of the instant invention nowhere mention the term "affixing". Instead the claims recite that the collection vessels include a wireless electronic memory tag, and that the tag remains directly attached to the vessels during their transportation, which is exactly what Berney teaches. Berney inherently discloses a plurality of vessels which are transported from one facility to another one thus providing distribution of the vessels among facilities.

The Appellants' assumption that the labels in Barney's disclosure are attached in the labs and will be removed in the labs does not have any basis, or sense. Also, recording specimen analysis data is the end of the custody chain.

It appears that the Appellants argue that attaching labels with RFID tags to the vessels at a specific facility make them patentable over the prior art, with which the examiner cannot agree.

Regarding obviousness rejections it appears the Appellants attack the references individually, which is not proper, see *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, the examiner believes that she provided clear motivations for modifying the primary references, and the mere statements that such modification is not obvious for a routineer in the art, is not persuasive.

Regarding rejection of the claims over Stevens in view of Moore, the examiner wonders, which hindsight was used in such rejection, when Moore specifically emphasizes benefits of using smart labels having an inexpensive RFID chip embedded in a self-adhesive paper label (other form factors would also be possible). "The label would typically have at least one barcode on it and the RFID chip would be encoded at the same time the barcode and human-readable information is printed on the label". This allows a direct modification of Stevens' two-partition barcode with attaching RFID chip to the permanent affixed portion of the label. Such modification will also be tamper-indicating. The examiner believes that the new rejection that she made in the Non-Final Office action is totally legitimate. The examiner does not believe that the Appellants may attack this rejection only on the bases that it was made after nine actions and five (?) examiner's answers. This is a proper rejection that has nothing to do with the hindsight. Moreover, the number of actions and Examiner's Answers is defined in the most part by the Appellants' amendments which also introduce new matter to the originally filed disclosure. Furthermore, it does not appear that the Appellants are arguing the essence of the rejection, but are rather attacking the examiner's application of the new rejections. This is not a proper argument related to the established rejection.

Further Appellants' arguments regarding obviousness rejections have the same problem of piecemeal analysis of references, in particular they attack the secondary references for not disclosing the subject matter of the primary references.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Yelena G. Gakh/
Primary Examiner AU 1777

Conferees:

/ROBERT J. WARDEN, Sr./
Supervisory Patent Examiner, Art Unit 1700*

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1777